

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ A solubilized paclitaxel composition comprising ~~4-90% by weight of at least one~~ 40 to 89.9% by weight of monoolein, ~~0.01-90% by weight~~ 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil, and ~~0.01-20% by weight~~ 0.01 to 10% by weight of paclitaxel so that the ratio of monoolein to oil is more than 1:1.

2-4. (Cancelled)

5. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 1, wherein said triglyceride is chosen from saturated and unsaturated triglycerides having ~~2-20 carbon atoms~~ 2 to 20 carbon atoms in each hydrocarbon chain.

6. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 1,

wherein said triglyceride is chosen from triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein;

wherein said iodized oil is chosen from Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil;

wherein said vegetable oil is chosen from soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil; and

wherein said animal oil is chosen from squalane and squalene.

7-9. (Canceled)

10. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 1 additionally comprising ~~0.01-5% by weight~~ 0.01 to 5% by weight of an additive.

11. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 10, wherein the additive is chosen from Cremophor, tocopherol, tocopherol acetate, a fatty acid, a fatty acid ester, a fatty acid alcohol, an insoluble drug, an alcohol and a polyol.

12. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 11, wherein the insoluble drug is chosen from an anticancer drug, a p-glycoprotein inhibitor and a hepatic metabolism blocker; wherein the alcohol is chosen from methanol, ethanol, propanol and isopropanol; and wherein ~~to~~ the polyol is chosen from ethyleneglycol, propyleneglycol and polyethyleneglycol.

13. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 12, wherein the anticancer drug is chosen from doxorubicin, cisplatin, carboplatin, carmustin (BCNU), dacarbazine, etoposide, 5-fluorouracil and a paclitaxel derivative chosen from docetaxel, bromotaxel and taxotere; wherein said p-glycoprotein inhibitor is chosen from cinchonin, a calcium channel blocker, a calmodulin antagonist, an antihypertensive, a Vinca alkaloid, a steroid, an antiarrhythmic, an anthelmintic and an immunosuppressant; and wherein said hepatic metabolism blocker is chosen from an anticancer drug chosen from cyclosporin A, doxorubicin, etoposide (VP-16) and cisplatin, verapamil and tamoxifen.

14-15. (Canceled)

16. (Withdrawn) The composition for solubilization of paclitaxel according to Claim 13, wherein the calcium channel blocker is chosen from verapamil and a dihydropyridine chosen from nifedipine, nicardipine and nitrendipine; wherein the calmodulin antagonist is chosen from trifluoroperazine; wherein the antihypertensive is reserpine; wherein the Vinca alkaloid is chosen from vincristine and vinblastine; wherein the steroid is progesterone; wherein the antiarrhythmic is chosen from amiodarone and quinidine; wherein the anthelmintic is chosen from quinacrine and quinine; and wherein the immunosuppressant is chosen from cyclosporine A, staurosporine and tacrolimus.

17-26. (Canceled)

27. (Currently Amended) ~~The composition for solubilization of paclitaxel—The solubilized paclitaxel composition~~ according to Claim 1, wherein ~~the administration route is chosen from—~~ the composition is suitable for oral administration, buccal administration, mucosal administration, intranasal administration, intraperitoneal administration, subcutaneous injection, intramuscular injection, transdermal administration, or intratumoral injection.

28. (Withdrawn) A method of preparing the composition for solubilization of paclitaxel according to Claim 1, wherein said method comprises the steps of:

(1) solubilizing 4~90% by weight of monoolein in 0.01~90% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil so that the ratio of monoolein to oil is more than 1:1; and

(2) solubilizing completely 0.01~20% by weight of paclitaxel in said mixture in step (1) by stirring.

29. (Withdrawn) The preparation method according to Claim 28, wherein the said mixture is heated to 50°C in step (1) to speed up the solubilization process.

30. (Withdrawn) The preparation method according to Claim 28, wherein the said mixture is heated to 50°C and sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

31. (Withdrawn) A method of preparing the composition for solubilization of paclitaxel according to Claim 1, wherein said method comprises the steps of mixing 4~90% by weight of monoolein, 0.01~90% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil and 0.01~20% by weight of paclitaxel so that the ratio of monoolein to oil is more than 1:1 and solubilizing completely.

32. (Withdrawn) The preparation method according to Claim 31, wherein the said mixture is heated to 50°C and sonicated in a bath type sonicator to speed up the solubilization process.

33. (Withdrawn) A composition for solubilization of paclitaxel including emulsifier comprising 4~90% by weight of at least one monoolein, 0.01~90% by weight an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil, 0.01~90% by weight of at least one emulsifier and 0.01~20% by weight of paclitaxel so that the ratio of monoolein to oil is more than 1:1.

34-36. (Cancelled)

37. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein said triglyceride is chosen from saturated and unsaturated triglycerides having 2~20 carbon atoms in each hydrocarbon chain.

38. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein said triglyceride is chosen from triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein; wherein said iodized oil is chosen from Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil; wherein said vegetable oil is chosen from soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil; and wherein said animal oil is chosen from squalane and squalene.

39-41. (Cancelled)

42. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein said emulsifier is chosen from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and bile acid.

43. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 42, wherein said phospholipid is chosen from a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup; wherein said non-ionic surfactant is chosen from a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij); wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative, and sodium dodecyl sulfate (SDS); wherein said cationic surfactant is chosen from 1,2-dioleoyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleoyl-3-ethylphosphocholic acid (DOEPC) and 3 β -[N-[(N',N'-dimethylamino)ethan]carbamoyl]cholesterol (DC-Chol); and wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

44-47. (Cancelled)

48. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33 additionally comprising 0.01~5% by weight of other additives.

49. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 48, wherein said other additives are chosen from Cremophor, tocopherol, tocopherol acetate, a fatty acid, a fatty acid ester, a fatty acid alcohol, an insoluble drug, an alcohol and a polyol.

50. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 49, wherein said insoluble drugs are chosen from an anticancer drug, a p-glycoprotein inhibitor and a hepatic metabolism blocker; wherein the alcohol is chosen from methanol, ethanol, propanol and isopropanol; and wherein the polyol is chosen from ethyleneglycol, propyleneglycol and polyethyleneglycol.

51. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 50, wherein the anticancer drug is chosen from doxorubicin, cisplatin, carboplatin, carmustin (BCNU), dacarbazine, etoposide, 5-fluorouracil and paclitaxel derivatives wherein the paclitaxel derivative is chosen from docetaxel, bromotaxel and taxotere;

wherein the p-glycoprotein inhibitor is chosen from cinchonins, calcium channel blockers, calmodulin antagonists, Vinca alkaloids, antiarrhythmics, steroids, antihypertension drugs, anthelmintics and immunosuppressants; and wherein the hepatic metabolism blocker is chosen from an anticancer drug chosen from cyclosporin A, doxorubicin, etoposide (VP-16) and cisplatin, verapamil and tamoxifen.

52-53. (Cancelled)

54. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 51, wherein the calcium channel blocker is a dihydropyridine chosen from verapamil, nifedipine, nicardipine and nitrendipine; wherein said calmodulin antagonist is trifluoroperazine; wherein the antihypertension drug is reserpine; wherein the Vinca alkaloid is chosen from vincristine and vinblastine; wherein the steroid is progesterone; wherein the antiarrhythmic is chosen from amiodarone and quinidine; wherein the anthelmintic is chosen from quinacrine and quinine; and wherein the immunosuppressant is chosen from cyclosporins, staurosporin and tacrolimus.

55-64. (Cancelled)

65. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein the administration route is chosen from oral administration, buccal administration, mucosal administration, intranasal administration, intraperitoneal administration, subcutaneous injection, intramuscular injection, transdermal administration and intratumoral injection.

66. (Withdrawn) A method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein said method comprises the steps of:

(1) preparing the viscous liquid by mixing 4~90% by weight of monoolein, 0.01~90% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil and 0.01~90% by weight of emulsifier so that the ratio of monoolein to oil is more than 1:1 by heating to below 50°C (step 1); and

(2) preparing homogeneous mixture by solubilizing completely 0.01~20% by weight of paclitaxel in said mixture in step (1) (step 2).

67. (Withdrawn) The method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 66, wherein the said mixture is heated to 50°C in step (1) to speed up the solubilization process.

68. (Withdrawn) The method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 66, wherein the said mixture is heated to 50°C in step (2) to speed up the solubilization process.

69. (Withdrawn) The method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 66 wherein the said mixture is sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

70. (Withdrawn) A method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein said method comprises the steps of:

- 1) preparing the paclitaxel solution by solubilizing 0.01~20% by weight of paclitaxel in 0.01~90% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil by sonicating in a bath type sonicator (step 1); and
- 2) preparing homogeneous mixture by mixing the paclitaxel solution in step (1) and 0.01~90% by weight of emulsifier and 4~90% by weight of monoolein so that the ratio of monoolein to oil is more than 1:1 (step 2).

71. (Withdrawn) The method of preparing the composition for solubilization of paclitaxel including emulsifier according to Claim 70, wherein the said mixture is heated to 50°C and sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

72. (Currently Amended) ~~The composition for solubilization of paclitaxel. The solubilized paclitaxel composition including emulsifier~~ according to Claim 1, wherein the said composition is liquid or semi-solid state at room temperature and includes an emulsifier.

73. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 1, comprising ~~41.5-66% by weight~~ 41.5 to 66% by weight of monoolein, ~~27-41.5% by weight~~ 27 to 41.5% by weight of an oil ~~selected from a group consisting of~~ chosen from triglyceride, iodized oil, vegetable oil and animal oil and ~~0.4-3% by weight~~ 0.4 to 3% by weight of paclitaxel.

74. (Withdrawn) The composition for solubilization of paclitaxel including emulsifier according to Claim 33, wherein the said composition is liquid or semi-solid state at room temperature.

75. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 1, which further comprises ~~0.01-90% by weight~~ 0.01 to 90% by weight of at least one emulsifier.

76. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 75, wherein said emulsifier is chosen from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and bile acid.

77. (Currently Amended) ~~The composition for solubilization of paclitaxel~~ The solubilized paclitaxel composition according to Claim 76,

wherein said phospholipid is chosen from a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup;

wherein said non-ionic surfactant is chosen from a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij);

wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative, and sodium dodecyl sulfate (SDS);

wherein said cationic surfactant is chosen from 1,2-dioleyl-3-trimethylammonium

propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB),
N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA),
1,2-dioleoyl-3-ethylphosphocholic acid-1,2-dioleoyl-3-ethylphosphocholic acid (DOEPC) and 3 β -[N-
[(N',N'-dimethylamino)ethan]carbamoyl]cholesterol (DC-Chol); and

wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

78. (New) A solubilized paclitaxel composition consisting essentially of 40 to 89.9% by weight of monoolein; 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil; and 0.01 to 10% by weight of paclitaxel.